# PROACTIV PLUS COMPLEXION PERFECTING HYDRATOR- salicylic acid lotion Guthy-Renker LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### **Proactiv+ Complexion Perfecting Hydrator**

**Drug Facts** 

#### **Active ingredient**

Salicylic Acid 0.5%

## Purpose

Acne Treatment

#### Use

for the management of acne.

### **Warnings**

#### For external use only

# When using this product

- do not use this product more than three times per day.
- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

#### Stop use and ask a doctor

If irritation becomes severe.

#### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- *Sensitivity Test for a New User*: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- cleanse the skin thoroughly before applying this product.
- cover the entire affected area with a thin layer one to three times daily.
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

#### **Inactive ingredients**

water, butylene glycol, cetearyl alcohol, dimethicone, sodium polyacrylate, scutellaria baicalensis root extract, sophora angustifolia root extract, morus alba root extract, glycyrrhiza glabra (licorice) root

extract, arctostaphylos uva ursi leaf extract, kojic acid, zinc gluconate, alpha-glucan oligosaccharide, sodium hyaluronate, bisabolol, allantoin, squalane, safflower oil/palm oil aminopropanediol esters, C12-15 alkyl lactate, caprylic/capric triglyceride, caprylyl glycol, ethylhexylglycerin, glycerin, ethylhexyl palmitate, hydrogenated polydecene, hydroxypropyl cyclodextrin, PPG-5 laureth-5, polyquaternium-11, ceteareth-20, aluminum starch octenylsuccinate, polysorbate 60, hexylene glycol, PPG-2 myristyl ether propionate, sodium hydroxide, disodium EDTA, phenoxyethanol, fragrance

#### Questions or comments?

Within US **1-800-950-4695** 

Dist. by: Guthy-Renker® LLC • PO Box 14383 Palm Desert, CA 92255-4383

#### PRINCIPAL DISPLAY PANEL - 89 mL Jar Box

Rodan & Fields **proactiv**<sup>+</sup>

Complexion Perfecting Hydrator

3 FL. OZ. 89 mL

salicylic acid acne treatment



# PROACTIV PLUS COMPLEXION PERFECTING HYDRATOR

salicylic acid lotion

**Product Information** 

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11410-010

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETO STEARYL ALCO HOL (UNII: 2DMT128 M1S)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
MORUS ALBA ROOT (UNII: CST1G9BZGD)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)	
KOJIC ACID (UNII: 6K23F1TT52)	
ZINC GLUCO NATE (UNII: U6 WSN5SQ1Z)	
.ALPHAGLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
LEVOMENOL (UNII: 24WE03BX2T)	
ALLANTO IN (UNII: 344S277G0Z)	
SQUALANE (UNII: GW89575KF9)	
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HYDRO GENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
PPG-2 MYRISTYL ETHER PRO PIO NATE (UNII: 88R97D8U8A)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:11410-010-49	1 in 1 BOX				
1		89 mL in 1 JAR; Type 0: Not a Combination Product				
2	NDC:11410-010-43	1 in 1 BOX				
2		29.57 mL in 1 JAR; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part333D	03/01/2013			

# Labeler - Guthy-Renker LLC (608315453)

Revised: 2/2016 Guthy-Renker LLC